

REMARKS

Claims 1 and 3-36 are pending. Claim 2 is canceled.

Support for Amendments

Claims 1 and 3-24, 26, and 29-36 are amended. The claims are amended for idiomatic English and to remove improper multiple dependencies. Claim 1 is amended to incorporate the elements of claim 2. Support for the amendments can be found in the claims as originally presented.

The abstract is reworded to be less than 150 words in length. Support for the amendment can be found in the original abstract.

Amendments to the Drawings are submitted herewith in Replacement Sheets.

No new matter is entered.

Objections

The Examiner indicates that new drawings are required because the original drawings are too dark to allow review of the data. Attached herewith are corrected drawings that are submitted in "Replacement Sheets." Applicants request entry of the drawings. No new matter is added. Applicants respectfully request withdrawal of the objection.

The Examiner requires a substitute specification in idiomatic English with corrected headings. Applicants respectfully traverse the objection on the basis that Applicants are entitled to be their own lexicographers, and that the specification is definite within the statutory requirements for a patent specification. Applicants respectfully request deferral of the expense of re-translating the application until further prosecution on the merits has occurred.

The Examiner requires a substitute abstract in idiomatic English. The abstract as amended is less than 150 words in length. Applicants respectfully request withdrawal of the objection.

Claims 8-36 are objected to for improper multiple dependencies and are not further examined at this time. Claims 8-36 are amended to remove improper multiple dependencies. Applicants request withdrawal of the objection. Upon withdrawal of the objection, Applicants are entitled to examination of all claims.

Claims 1-7 are objected to for non-idiomatic English. By amendment, claims 1-7 are presented in idiomatic English. Applicants request withdrawal of the objection.

Rejection Under 35 USC § 112, 2nd paragraph: Indefinite

Claims 1-7 are rejected under 35 USC § 112, 2nd paragraph, for being indefinite due to non-idiomatic English. By amendment, claims 1-7 are presented in idiomatic English. Applicants request withdrawal of the rejection.

Rejection Under 35 USC § 112, 1st paragraph: Scope of Enablement

Claims 1-7 are rejected under 35 USC § 112, 1st paragraph, for lack of enablement for the scope of the claims, particularly with respect to SEQ ID NOs 1 and 2. Applicants respectfully request withdrawal of the rejection as moot in view of the amendments to claim 1.

According to the data of HMC in Fig. 1A (mesangial cells: filled in black) in Yamamura (Cancer Res 61: 3969-3977; Applicant's IDS) that was also cited in the instant

specification, high luciferase activity was observed at the -288 and -260, but a significant decrease in the luciferase activity was observed at -219. This has indicated that the region including the base sequence from -260 to -219 shown in SEQ ID NO.: 1 is an essential region for regulation of a transcriptional initiation in a human calponin gene promoter.

Rejection Under 35 USC § 102(b)

Claims 1 and 6 are rejected under 35 USC § 102(b) as being anticipated by U.S. Patent 5,728,379 (Martuza). Applicants respectfully traverse. Claim 1 is amended to include the elements of claim 2. Martuza is silent with respect to SEQ ID No.1. Applicants respectfully request withdrawal of the rejection.

Rejections Under 35 USC § 103(a)

Claims 1-7 are rejected under 35 USC § 103(a) as being obvious over Martuza (U.S. Patent 5,728,379) in view of Yamamura (Cancer Res 61: 3969-3977, cited in the IDS). Applicants respectfully traverse on the basis that there is no reasonable expectation of success.

The Office Action states that

One would have had a reasonable expectation of success because Yamamura expresses a clear desire to make exactly this vector which would have “improve efficacy and safety for preclinical and clinical testing (page 3976, column 1, first paragraph).

(Office Action, page 10, paragraph 28). However, the passage quoted in the Office Action provides no basis for a reasonable expectation of success. On the contrary, the passage merely indicates the desirability of making HSV strains that carry an intact TK gene. Yamamura provides no data to verify the properties of such strains, nor does Yamamura provide an enabling disclosure for making such strains. Martuza fails to remedy the deficiencies of Yamamura

because Martuza fails to provide any information on making HSV strains that carry an intact TK gene with the SEQ ID Nos as claimed. Therefore, the Office Action fails to show a reasonable expectation of success in combining the references.

In this regard, attached herewith is a “Declaration” signed by Dr. Hisako Yamamura who is the main author of Yamamura (Cancer Res 61: 3969-3977). In the “Declaration,” Dr. Hisako Yamamura states that the present invention could not have been reached even if Yamamura (Cancer Res 61: 3969-3977) and Martuza (U.S. Patent 5,728,379) were combined.

Claims 1-7 are rejected under 35 USC § 103(a) as being obvious over Takahashi (U.S. 2004/0197308) in view of Martuza (U.S. Patent 5,728,379) and in view of Yamamura (Cancer Res 61: 3969-3977). Applicants respectfully traverse on the basis that Takahashi is not available as prior art. Takahashi published on October 7, 2004 (after the filing date of the instant application) from US 10/477,797 and could therefore only be theoretically available as prior art under 35 USC § 102(e). However, Takahashi does not have a “35 USC § 102(e) date” because it is a 371 application of an international application that was not published in English. [See Example 5 in the MPEP 706.02(f)(1) for an example of applying 35 USC § 102(e).] Therefore, Applicants request withdrawal of the rejection because Takahashi as cited is not available as prior art.

With regard to PCT/JP02/04334 from which the cited Takahashi reference entered the national phase, the PCT application published as WO 02/092816 on November 21, 2002, which is after the filing dates of the JP applications from which the instant application claims

priority (December 28, 2001 and August 30, 2002 respectively). Therefore, the PCT application from which Takahashi entered the national phase in the US is similarly not available as prior art.

Rejection for Obviousness-type Double Patenting

Claims 1-7 are provisionally rejected for obviousness-type double patenting over Takahashi (U.S. application 10/477,797) in view of Martuza (U.S. Patent 5,728,379) and in view of Yamamura (Cancer Res 61: 3969-3977). Applicants respectfully traverse. In addition, Applicants respectfully request that the rejection be held in abeyance until an indication of allowable subject matter. A request for holding the provisional rejection in abeyance is proper. Applicants note that it is proper when dealing with otherwise allowable subject matter in co-pending applications to withdraw a provisional rejection in the most advanced application, allow it to issue, and make a (non-provisional) rejection in the remaining applications. See MPEP 804 (I) (B).

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

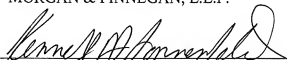
The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 4439-4022.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 4439-4022.

Respectfully submitted,
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